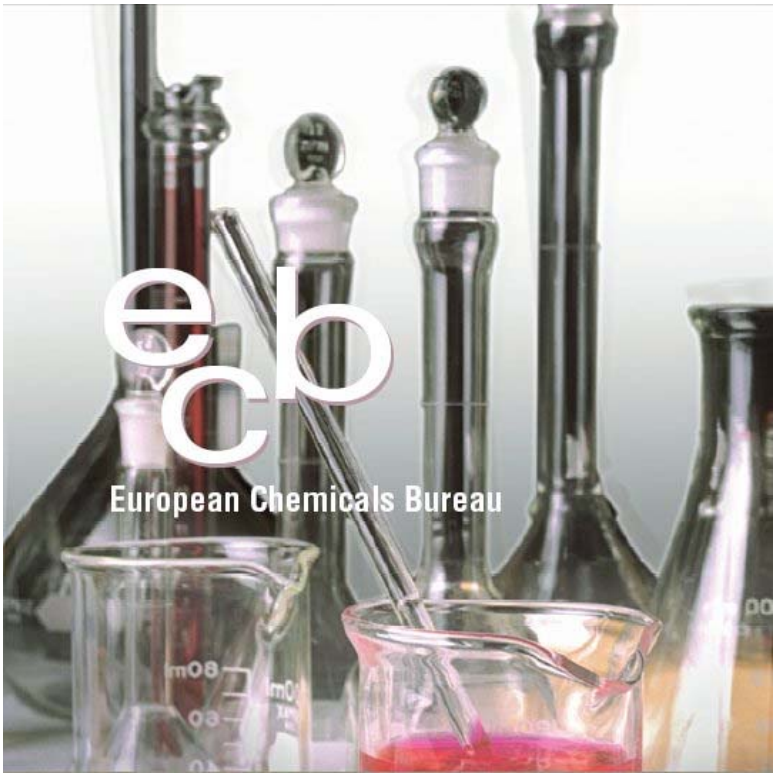
JRC Scientific and Technical Reports

The European Chemicals Bureau: an overview of 15 years experience in EU chemicals legislation

Institute for Health and Consumer Protection
European Chemicals Bureau



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JRC EUROPEAN COMMISSION

ihcp Institute for Health and Consumer Protection

The mission of the IHCP is to protect the interests and health of the consumer in the framework of EU legislation on chemicals, food, and consumer products by providing scientific and technical support including risk-benefit assessment and analysis of traceability.

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EXECUTIVE SUMMARY

From its creation in 1993, the European Chemicals Bureau (ECB) has played a vital role in the conception, development, implementation and monitoring of European Union (EU) legislation on chemicals and in contributing to the European Commission's participation in international chemicals programmes.

The ECB has housed much of the European Commission's experience, capacity and historical memory in chemical risk assessment and safe chemical management. The contribution of ECB to the drafting, development and implementation of the REACH regulation has been an important one. The provision of scientific/technical expertise to the start-up phase of the newly born European Chemicals Agency (ECHA) has been essential for a swift and effective implementation of REACH. The ECB has contributed to that effort not only by selecting, recruiting and training ECHA staff but also by seconding part of its own key staff to the agency. And finally, during 2008 the ECB is completing the hand-over files and transmitting them to the ECHA, which is taking over responsibility for the operational implementation of EU legislation on chemicals.

This report, which is produced on the 15th anniversary of the ECB, provides a historical overview of ECB's scientific and policy support activities since its establishment in 1993 as part of the European Commission's Joint Research Centre (JRC).

Since its early beginning, the mission of the ECB has been to provide scientific and technical support to the conception, development, implementation and monitoring of EU policies on dangerous chemicals. Following the entry into force of the REACH regulation on 1 June 2007, a number of ECB activities are being completed during the course of 2008. In order to ensure a smooth transition, a range of guidance documents, software tools and databases are being formally handed over to the ECHA. However, other ECB activities (notably on biocides, computational toxicology and testing methods) will continue to be carried out and developed further within the JRC's Institute for Health & Consumer Protection (IHCP). In this way, even though the designation of ECB will cease to exist, the JRC will continue to provide science-based policy support, not only to REACH, but also to other pieces of EU chemicals legislation.

ACRONYMS AND ABBREVIATIONS

BPD	Biocidal Products Directive
C&L	Classification and Labelling
CA	Competent Authority
CAS	Chemical Abstract Service
CLP	Classification, Labelling and Packaging
DART	Decision Analysis by Ranking Techniques
DES	Data Entry Screen
DG	Directorate General
DNA	Designated National Authority
DSD	Dangerous Substances Directive
ECB	European Chemicals Bureau
ECHA	European Chemicals Agency
ECVAM	European Centre for the Validation of Alternative Methods
EDEXIM	European Database Export Import of Dangerous Chemicals
EEC	European Economic Community
EI	Environment Institute
EINECS	European INventory of Existing Commercial Substances
ELINCS	European LIst of Notified Commercial Substances
ESIS	European Chemical Substances Information System
ESR	Existing Substances Regulation
EU	European Union
EURAM	EU Risk Ranking Method
EUSES	European Union System for the Evaluation of Substances
FAO	Food and Agriculture Organisation
GHS	Globally Harmonized System
HEDSET	Harmonised Electronic Data Set
HPV	High Production Volume
IHCP	Institute for Health and Consumer Protection
IPCS	International Programme on Chemical Safety
IRAS	Institute of Risk Assessment Sciences
IUCLID	International Uniform ChemicaLs Information Database
IUPAC	International Union of Pure and Applied Chemistry
JRC	Joint Research Centre
LPV	Low Production Volume
MEP	Member of European Parliament
MITI	Ministry of International Trade and Industry
MOD	Manual of Decisions
MS	Member State
NCD	New Chemicals Database
NCM	National Coordinators Meeting
NGOs	Non-Governmental Organisations
OECD	Organisation for Economic Cooperation and Development
ORATS	Online Risk Assessment Tracking System
PIC	Prior Informed Consent
QSAR	Quantitative Structure-Activity Relationship
REACH	Registration Evaluation Authorisation and Restriction of Chemicals
REACH-IT	Registration Evaluation Authorisation and Restriction of Chemicals Information Technology
RIP	REACH Implementation Project
RIVM	National Institute for Public Health
SAR	Structure-Activity Relationship
SEG	Stakeholder Expert Group
SNIF	Structured Notification Interchange Format
TC C&L	Technical Committee for Classification and Labelling
TGD	Technical Guidance Document
TMR	Testing Methods Regulation
UN	United Nations
UNCED	United Nations Conference on Environment and Development
UNEP	United Nations Environment Programme
US EPA	United States Environmental Protection Agency
WNT	Working Group of National Co-ordinators of the Test Guidelines Programme

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THE ECB - A SHORT HISTORY

The European Chemicals Bureau (ECB) was created in 1993 as a unit within the European Commission's Joint Research Centre (JRC) [1]. For 15 years, the ECB has provided scientific and technical support to the conception, development, implementation and monitoring of EU policies on dangerous chemicals. This support has included managing the risk assessment process for New and Existing Chemicals, the authorisation process for biocides, and the classification and labelling of hazardous chemicals. The ECB has also played a leading role in the development and harmonisation of testing methods and non-testing methods (e.g. computer-based models), and in the development of guidance documents and tools in support of the REACH (Registration, Evaluation, Authorisation and Restriction of Chemicals) regulation [2]. As a result of these activities, the ECB is now renowned for ensuring the development of methodologies and software tools necessary for the regulatory assessment of chemicals in a systematic manner.

The European Union's chemical industry produces about one third of the world's chemicals and employs 1.7 million people, while millions of others work in industries such as car production or textiles, which are major users of chemicals. Thus, the role of the ECB has been of great importance and relevance, given the scale of the chemicals industry.

With the repeal of current EU legislation on chemicals and the recent creation of the European Chemicals Agency (ECHA), responsible for implementing REACH [2], the ECB is completing several activities or transferring them to the ECHA. In particular, from 1 June 2008, the ECB will accomplish its activities supporting the Dangerous Substances Directive (DSD) [3] and the Existing Substances Regulation (ESR) [4].

The JRC will continue its scientific support to EU legislation on biocides [5] and on the export and import of dangerous chemicals [6], as well as the new draft Testing Methods Regulation (TMR), which is considered crucial for REACH implementation. In addition, the expertise in risk assessment methodologies and computational toxicology will be used to support REACH and the ECHA, as well as chemical assessment needs under other pieces of legislation.

The ECB has evolved from a handful of motivated and dedicated people in 1993 to around 60 staff in 2007. Following the establishment of the ECHA, four permanent members of staff were seconded to Helsinki to support the build up of the agency, and many other colleagues (more than 10 with short term contracts) have also left to take up new duties in the agency. In addition, 20 trainees who were prepared in 2006-2007 at the ECB are now working for the agency.

As a celebration of 15 years' experience and accomplishments, this report summarises key aspects of ECB's role, including its vital contribution to the risk assessment of chemicals and to the development of REACH and other regulatory and scientific programmes which are neither superseded by REACH nor transferred to the ECHA (e.g. biocides, computational toxicology, export/import). From 1 June 2008, these activities will continue within the JRC's Institute for Health and Consumer Protection (IHCP).

THE BEGINNING AND EVOLUTION OF ECB ACTIVITIES

The sixth amendment of the Dangerous Substances Directive (DSD) [7] introduced the concept of "existing" and "new" substances and provided for the establishment of a definitive inventory of 'existing' substances called EINECS (the European INventory of Existing Commercial Substances). The Directorate General (DG) of the Commission responsible for EU legislation on chemical substances (former DG XI; now DG Environment) requested the support of the JRC to set up the EINECS database, including some 100,000 entries reported to occur on the EU market prior to 18 September 1981. This major project started with a design study at the end of 1978 and resulted in the publication of EINECS in the *Official Journal* at the end of 1990 [8].

Friedrich Geiss, Director of the Environment Institute, father of the ECB

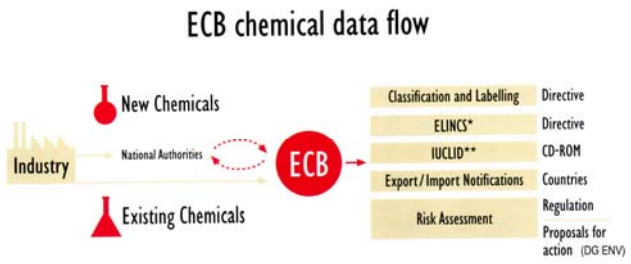
The success of this project prompted DG XI to seek further support from the JRC to implement the industrial chemicals legislation. Consequently, following a Commission Communication to the Council and the European Parliament, the ECB was formally established within the former Environment Institute (EI) of the JRC on 1 January 1993 [1], with the aim of carrying out and coordinating the scientific and technical work needed for the implementation of EU legislation in the area of chemicals control.

The tasks of the ECB were initially organised according to the following major work areas:

- Classification and labelling of dangerous substances (*Directive 67/548/EEC*)
- Testing methods (*Directive 67/548/EEC*)
- Notification of New Substances (*Directive 67/548/EEC*) and their risk assessment (*Directive 93/67/EEC*)
- Data collection and risk assessment of Existing Substances (*Regulation (EC) 793/93 and 1488/94*)
- Export/Import control of dangerous chemicals (*Regulation (EC) 2455/*92 and subsequently *Regulation (EC) 304/2003*)

The ECB assumed an increasingly important role in the assessment, management and control of risks that may be posed by chemical substances circulating in the EU. Subsequently, ECB's portfolio was extended to include additional tasks:

- Authorisation of biocides (*Directive 98/8/EC*) in 1997, and
- Computational toxicology as scientific support to chemicals legislation in 2003.



ECB chemical data flow

In 1998, the JRC underwent a major re-organisation and the ECB, together with other units active in life sciences and consumer products were united to form the Institute for Health and Consumer Protection (IHCP).

Picture of ECB building in 2007

In 2000, on the basis of an ECB study on the availability of data for existing substances [9, 10], the European Parliament started a debate on the need for a new chemicals policy and in February 2001 the Commission issued a White Paper [11]. Subsequent elaboration among stakeholders resulted in the release of a Commission proposal [12] for the REACH regulation. DG Environment and DG Enterprise, jointly responsible for REACH, sought support from the ECB to ensure a smooth transition from the 'old' to the 'new' chemicals legislation, which led to another task: REACH support, including informatics applications for REACH (known as REACH-IT)

Following further political debate, the REACH regulation [2] was adopted by the Council and Parliament on 18 December 2006. The REACH regulation entered into force on 1 June 2007, to become operationally effective from 1 June 2008. In parallel with the development of the legal framework of REACH, the ECHA was established in Helsinki as the administrative centre for coordinating the operational implementation of the legislation. As a consequence, in 2008 the JRC will hand over to the ECHA the ECB activities concerning the DSD and the Existing Substances regulation (ESR), as well as a range of guidance documents developed for the implementation of REACH.

ECB Fields of Activity to be accomplished in 2008

Classification and Labelling of Chemicals

Classification has an essential role in identifying the intrinsic properties of dangerous chemicals (substances and preparations in the form of e.g. industrial chemicals, household chemicals, pesticides and biocides), and it is therefore important and

relevant for the protection of occupational users, consumers and the environment. Classification is directly linked to labelling, which is one of the most important ways to communicate the hazard information to the users of chemicals. For consumers, the labelling is most often the only source of hazard information. The rules for classification and labelling (C&L) are defined in the DSD for substances and in *Directive 1999/45/EC* for preparations.

A selection of hazard symbols used in the labelling of substances and preparations

Classification is not only linked to the labelling of hazardous chemicals[1], but also has a huge impact on the control of chemicals, as it leads to a number of different measures to reduce the risk of classified chemicals. At least 20 pieces of downstream legislation are affected by the C&L provisions in the DSD, including legislation regulating pesticides, biocides, consumer products, and cosmetics.

The ECB has played a key role in the classification and labelling process. It has been responsible for the scientific and technical preparation of the Commission's proposals to update the annexes to the DSD. This includes Annex I, which contains the legally binding list of dangerous substances for which harmonised classification and labelling have been agreed at Community level in accordance with the criteria and the procedures laid down in the DSD.

To prepare the proposals for the classification and labelling of substances, as well as updating of the classification criteria, the ECB coordinated and chaired the Technical Committee for Classification and labelling (TC C&L). The TC C&L was an expert committee with nominees from government authorities, industry and Non-Governmental Organisations (NGOs), as well as observers from Candidate Countries. Since 1994, the ECB has held more than 110 meetings on physical chemical properties, health and environmental effects of existing chemicals, biocides, pesticides and new chemicals. In addition, to address specific and important scientific issues, the ECB organised specialised expert meetings in the fields of reproductive toxicity, carcinogenicity, mutagenicity and sensitisation. As a result, the ECB has coordinated the development of guidance documents on various classification topics, e.g. potency of carcinogens, potency of sensitisers, haemolytic anaemia and parental toxicity (within reproductive toxicity).

In the current version of Annex I, 3366 entries are listed, including ~7900 substances. The entries are often entries for groups of substances. The list can be searched on-line, according to either generic (e.g. R-phrase) or specific (e.g. CAS number) criteria, by using the CLASSLAB database which is accessible via the ECB website[2]. The CLASSLAB database is one of the few on-line searchable databases with substance names translated into at least 11 languages.

The other annexes to the DSD provide official references of, respectively: hazard symbols (Annex II); R-phrases (Annex III); S-phrases (Annex IV); testing methods (Annex V); and C&L criteria (Annex VI). The texts of these annexes are also available via appropriate links on the ECB website.

A new EU regulation on the classification, labelling and packaging of substances and mixtures (the "CLP regulation") is currently undergoing the co-decision procedure in the Council and the Parliament to bring the European legislation into line with the Globally Harmonised System for classification and labelling of chemicals developed within the United Nations. In support of this important process, the ECB is currently coordinating the development of a guidance document for the new CLP Regulation.

During the course of 2008, the ECB activities on the C&L of dangerous chemicals will be handed over to the ECHA.

Notification of New Substances

A notification scheme for "new" substances, proscribing a pre-marketing hazard assessment for novel substances not reported in EINECS, has been operational since 1983, in accordance with the sixth amendment of the DSD [3]. Annexes VII and VIII of this directive lay down the testing requirements. Subsequently, test requirements were expanded in the 7th amendment of the DSD [13] and principles of risk assessment were introduced in 1993 [14].

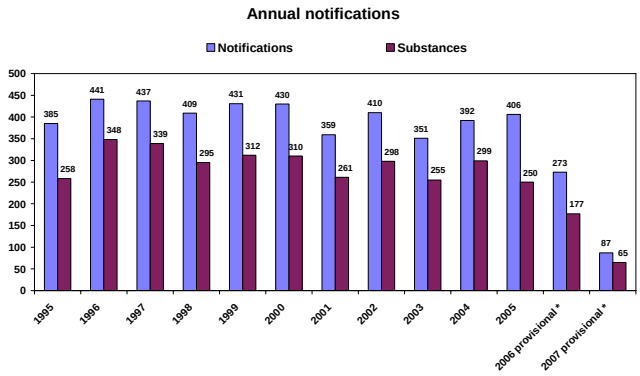
A full notification dossier includes comprehensive assay reports on substance properties and hazard assessment, submitted to the competent authority (CA) in the EU Member State (MS) where the substance is manufactured or imported. A summary version is also submitted to ECB which then distributes it to all MS CAs. Summary notifications are compiled in a standard electronic format called a

[1] http://ecb.jrc.ec.europa.eu/classification-labelling/

[2] http://ecb.jrc.ec.europa.eu/classification-labelling/search-classlab

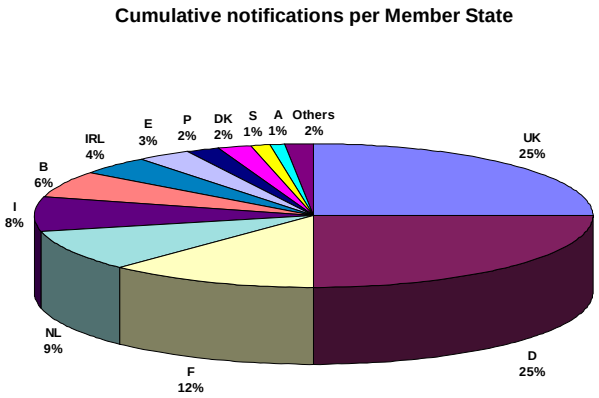
Structured Notification Interchange Format (SNIF) file. The data in SNIF files is obtained in compliance with official methods and standards and is reviewed by Member State regulators to ensure consistency (e.g. in implementation of hazard classification). SNIF files are treated as confidential among CAs and Commission services, with particular restriction on molecular identities and specific data. The ECB has housed these data in a secure area with restricted access.

The ECB has managed the notification scheme since April 1995, ensuring conformity control of all SNIF files and logging them in the New Chemicals Database (NCD). The ECB has received, processed and exported about 400 notifications per year. Notifications include multiple dossiers on identical substances, submitted by different manufacturers and importers. In addition, the ECB has dealt with hundreds of updates, classification and labelling proposals and follow-up correspondence (e.g. testing proposals).



Annual notifications of new substances to the ECB
** NCD status 31/01/2008,*
ECB continues to receive notifications from 2006 and 2007

The NCD registers ~8000 notifications, representing ~5000 substances. Notifications from the United Kingdom and Germany contribute about 25% each of the cumulative total, followed by France (12%), The Netherlands (9%) and Italy (8%). Foreign imports, particularly from USA, Japan and Switzerland, represent about half of new notified substances. Within the EU, the most important country for domestic manufacture is Germany, followed by UK and France. Most important uses are intermediates (about 25% of all notified chemicals) and colouring agents (about 14%). Other relevant categories are photochemicals, cosmetics (substances used as components of cosmetics and toiletry formulations), process regulators, odour agents and stabilisers. The majority of the substances are notified for production volumes between 1 and 10 per year. About 30% of the substances are produced in smaller and about 13% in higher volumes.



Cumulative notifications of new substances per Member State

The ECB is in charge of publishing ELINCS (European LIst of Notified Commercial Substances), which provides a periodically updated inventory of new chemicals, available via the ECB website[3]. ELINCS includes all trade names registered for a substance. International Union of Pure and Applied Chemistry (IUPAC) names are also cited in ELINCS, but only for substances with officially assigned classification and labelling.

By organising and chairing Technical and Scientific Meetings (twice a year) and Working Group Meetings on specific issues (e.g. polymers or reduced testing requirements for intermediates with limited exposure), the ECB has enabled MS CAs to discuss issues related to the notification scheme and to ensure a harmonised implementation of the directive. Since 2004, meetings have been carried out jointly with existing substances, looking for harmonised approaches between new and existing substances before REACH enters into force. The ECB collects decisions of these meetings in a Manual of Decisions (MoD), which is a reference of agreed interpretation of the legislation, ensuring uniform implementation, but without legal status. Scope ranges from general guidance to specific queries. The MoD (non-confidential version) is available via the ECB website[4].

Notified substances are considered as registered under REACH. Therefore, the information of the New Chemicals Database will be migrated to IUCLID 5 and handed over to ECHA.

[3] http://ecb.jrc.ec.europa.eu/new-chemicals/
[4] http://ecb.jrc.ec.europa.eu/new-chemicals/

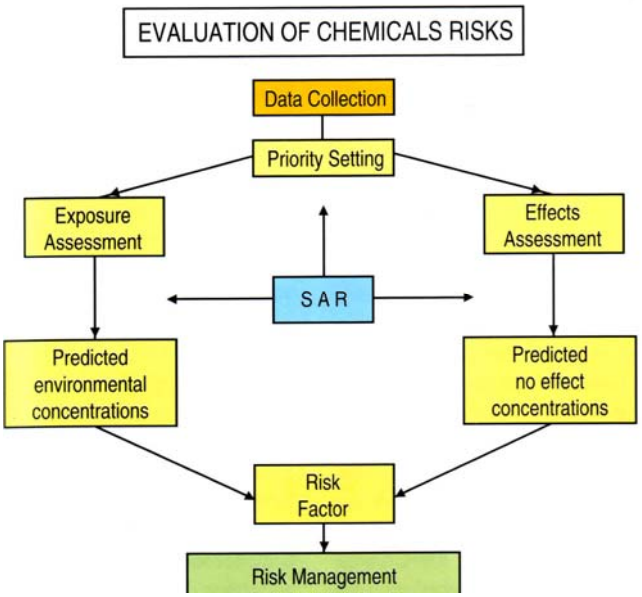
Existing Chemicals

Existing substances are those marketed prior to 18 September 1981 and established in EINECS, which includes some 100,000 entries. International concern regarding the potential risks of existing chemicals became a policy priority in the late 1980s. To address this concern in the then European Economic Community (EEC), the Commission proposed a number of legal instruments, including a regulation on the evaluation and control of risks of existing substances (*Council Regulation (EEC) 793/93*, also known as the Existing Substances Regulation [ESR]).

The ESR established a framework for a systematic evaluation of existing chemicals, differentiating high production volume (HPV) chemicals manufactured or imported at volumes greater than 1000 tonnes per year from low production volume (LPV) chemicals with a production or import volume between 10 and 1000 tonnes per year.

In accordance with the ESR, substance evaluations have been carried out in four principal phases: data collection, priority setting, risk assessment, and risk reduction. The ECB has played the leading role in the first three of these phases, and actively assisted DG Environment as far as risk reduction was concerned.

The ECB participated in the elaboration of harmonised procedures for priority setting and for the risk assessment of existing chemicals. The ECB was responsible for producing a ranking of the high production volume chemicals in close collaboration with MS CAs, industry and several international organisations. Subsequently, in a process coordinated by the ECB[5], substances on the priority list were subject to thorough risk assessments by the MS CAs, following the principles of risk assessment introduced in 1994 [15] and the guidance in the Technical Guidance Document on Risk Assessment (see below).



Evaluation of chemical risks

Data collection

The data collection process is divided into three separate data collection phases. In Phase I, Industry had to submit data on HPV chemicals listed in Annex I by 4 June 1994, whereas in phase II, Industry had to submit data on HPV chemicals not appearing in Annex I by 4 June 1995. The data were submitted in a standard format, HEDSET (Harmonised Electronic Data Set) to the ECB, where they were archived in IUCLID (International Uniform ChemicaL Information Database). In phase III, a limited dataset on Low Production Volume (LPV) chemicals had to be submitted by June 1998.

The data collection under the ESR programme revealed that for many existing substances, although put on the EU market in high volumes, basic studies to evaluate their effects on humans and the environment were missing [9, 10]. Furthermore, a systematic risk assessment was only foreseen for the priority substances. REACH will improve the

[5] http://ecb.jrc.ec.europa.eu/existing-chemicals/

knowledge concerning existing substances, for example by requiring a safety assessment for all substances manufacture/imported above 100 per year. Existing substances are so-called "phase-in substances" under REACH and require pre-registration and subsequently registration.

Information submitted by manufacturers/importers on ~2800 HPVs and ~7800 LPVs is currently accessible via the European Substances Information System (ESIS) on the ECB website[6].

Priority setting

To ensure a consistent review of the IUCLID database, the ECB developed EURAM (EU Risk RAnking Method) in consultation with industry and Member State authorities [16, 17]. The method was designed to rank substances according to their potential risk to humans and the environment. Since 1994, the Commission has published four priority lists, including in total 141 substances.

Risk Assessment and Risk Reduction

Substances on priority lists must undergo an in-depth risk assessment covering the risks posed by the priority chemical to humans (covering workers, consumers and humans exposed via the environment) and the environment (covering the terrestrial, aquatic and atmospheric eco-systems and accumulation through the food chain). This risk assessment follows the framework set out in the ESR and in the Technical Guidance Document (TGD) on risk assessment[7].

The ECB has played a leading role in the risk assessment phase. The first drafts of the risk assessment reports have been written by the MS authorities who act as rapporteurs. The ECB has then organised, chaired and followed up the meetings, seeking consensus on the conclusions of the risk assessments. The status of risk assessments for the priority substances is available via the ECB website, via the Online Risk Assessment Tracking System (ORATS) within ESIS[8].

As a follow-up to the risk assessment phase, the ECB supported DG Environment in the risk reduction phase, when necessary. In cases where the risk assessment of a substance leads to the conclusion "substance of concern, further risk reduction measures, beyond those already in place, are required", a risk reduction strategy is developed according to the Technical Guidance Documents on Risk Reduction. This may lead to restriction measures pertaining to various pieces of EU legislation, such as *Directive 76/769/EEC* (the "Limitations Directive"), the Water Framework Directive or the Integrated Pollution Prevention and Control Directive.

The Technical Guidance Document (TGD) on Risk Assessment

In support of the industrial chemicals legislation, in particular the directives on risk assessment for new notified substances [14] and existing substances [15], the ECB supported DG XI[9] in the production of the first version of the Technical Guidance Document (TGD) on Risk Assessment, which was published in 1996 [18]. This key guidance document was later revised, this time under ECB leadership, to take account of the experience gained when using it for risk assessments of about 140 existing substances and hundreds of new substances. Furthermore, it was expanded to address some of the needs of the Biocidal Products Directive (BPD) [5]. The second version of the TGD, published in April 2003 [19], made a valuable contribution to the development and harmonisation of risk assessment methodologies not only within the Community but also worldwide in the context of international activities within the Organisation for Economic Cooperation and Development (OECD) and the International Programme on Chemical Safety (IPCS).

2nd edition of the Technical Guidance Document (TGD) on Risk Assessment of Chemical Substances following European Regulations and Directives

The European Union System for the Evaluation of Substances (EUSES)

The European Union System for Evaluation of Substances (EUSES) is a decision-support system for the rapid evaluation of the risks of substances to humans and the environment posed by chemical substances. EUSES has been developed by the National Institute of Public Health and the Environment (RIVM) in The Netherlands, under contract to the ECB. The system is based on the guidance in the TGD on Risk Assessment.

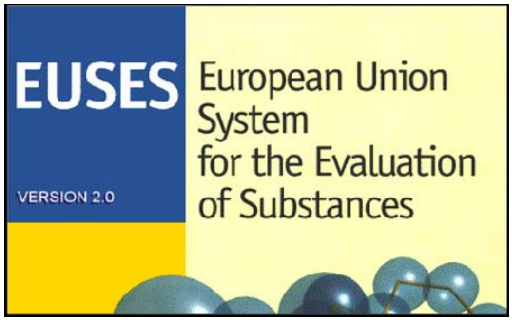
[6] http://ecb.jrc.ec.europa.eu/esis

[7] http://ecb.jrc.ec.europa.eu/tgd

[8] http://ecb.jrc.ec.europa.eu/esis

[9] The former name of DG Environment

The development of EUSES is steered by the EUSES Working Group, which is chaired by the ECB. The EUSES software can be downloaded (free of charge) from the ECB website[10].



REACH SUPPORT

In the beginning of the new millennium, the need for substantial reform of the chemicals legislation was identified, in particular the need to shift the "burden of proof" for safe use of chemicals from authorities to industry. The overall objective of REACH is to improve human health and the environment while maintaining the competitiveness of the chemicals industry. REACH provides for a coherent legislation, replacing about 40 pieces of existing legal text. It also aims to improve the communication and risk management in the entire chemical supply chain and to replace particularly dangerous chemical substances with safer alternatives.

The ECB has contributed significantly to all phases of drafting and implementation of REACH[11], including preparations for setting up the ECHA. In addition, ECB experts have provided training and given countless presentations at international seminars, conferences and workshops organised by various stakeholders.

Assessment of the possible impact of REACH on testing costs and animal testing

In 2003, the ECB published a report on the impact of REACH on the need for further testing under REACH, taking into account already existing obligations and voluntary initiatives and applying certain assumptions regarding the use of estimation techniques and the outcome of screening tests and risk assessments [20]. This report was followed up by an additional ECB assessment [21] which identified the potential savings of vertebrate test animals that could be obtained through application of these alternative approaches. These reports emphasised the importance, in terms of saving animals and reducing test costs, of using existing information and alternative methods, and particularly computer-based estimation methods and grouping approaches.

Preparation of legal text

The ECB was closely involved in the initial drafting of the legal text, in particular the aspects relating to scientific and technical issues. The ECB was also closely involved in the political negotiations, supporting the lead Commission services (DG Environment and DG Enterprise) and the European Parliament in relation to the technical and scientific content. During the political negotiations for REACH, Jack de Bruijn (ECB) acted as an independent advisor to Guido Sacconi, MEP and the European Parliament's lead Rapporteur on the REACH proposal.

Implementation

As mentioned elsewhere in this brochure, the ECB has contributed significantly to the development of IT tools for REACH. In addition, ECB has coordinated the work of developing guidance documents for Industry and Authorities in the REACH Implementation Projects (RIPs). These guidance documents, covering all aspects of REACH, have been developed in an open process in close cooperation with stakeholder experts (> 200) from EU Member States, Industry, NGOs, non-EU countries and international organisations. As part of this process, up to 50 Stakeholder Expert Group (SEG) meetings have been prepared and chaired by ECB staff. The process will result in about 15 guidance documents covering all aspects of REACH[12].

Setting up of the European Chemicals Agency (ECHA)

The ECB has contributed significantly to the preparations and start-up of the ECHA, not least by coordinating and carrying out a nine-month training program for about 20 technical and scientific staff of the agency, and by secondment of senior ECB staff to key managerial posts during the start-up phase of the agency. The ECB also coordinated the set-up of the ECHA website[13] where all REACH guidance is provided, including the development of the so-called

[10] http://ecb.jrc.ec.europa.eu/euses
[11] http://ecb.jrc.ec.europa.eu/reach/
[12] http://ecb.jrc.ec.europa.eu/reach/rip/
[13] http://echa.europa.eu/

"Navigator" assisting industry actors in identifying their obligations under REACH.

The ECHA started its work in Helsinki in June 2007 and will become fully operational from June 2008 onwards.

Although the products of the RIPs are being handed over to the ECHA, the JRC will continue to provide scientific and technical support to REACH after 1 June 2008.

ECB AS THE PROVIDER OF INFORMATION ON CHEMICALS

The role played by the ECB both at the EU and international levels in terms of providing information on chemicals to industry, government authorities, the scientific community and the general public has been an important one. In the spirit of UNCED Agenda 21, chapter 19, Programme Area (c) on "Information Exchange on Toxic Chemicals and Chemical Risks", it is the Commission's policy to make the developed tools available for all involved parties.

IUCLID

Since 1993, the Commission has developed and operated the International Uniform ChemicaL Information Database (IUCLID), hosted by the ECB[14]. IUCLID has been the primary tool for collecting and exchanging the data required for risk assessment within the EU Existing Chemicals Programme [22]. The system was developed by the Commission in close co-operation with the chemicals industry and the Member States. IUCLID was based on an earlier software package used by the some major chemical companies in Germany and the first Commission version was known as IUCLID 2.0.

During the data collection phase, the data were submitted by industry to the ECB, using the standard HEDSET format. The HEDSET program was a simple data entry program, which supported data entry in a structure similar to the data structure used by the IUCLID software. By the end of 1995, more than 9000 datasheets had been received by the ECB.

In 1998, IUCLID 3.0 was released. This new version of IUCLID had a client-server architecture and a graphical user interface.

In 1999, a notable development was the adoption, by the OECD Task Force on Existing Chemicals, of IUCLID as the system to be used within the OECD Existing Chemicals Programme. The OECD approval implied that the US Environment Protection Agency (EPA) and the Japanese Ministry of International Trade and Industry (MITI) would accept data sets in IUCLID format for reporting under their chemical programmes.

Version 4.0 of IUCLID was released in 2001. The new program and database were extended to support the reporting requirements for biocidal substances under the BPD (*Directive 98/8/EC*) [23].

While IUCLID versions 2-4 were relevant for European Regulations prior to REACH, the development of IUCLID 5, which started in 2005, constituted a complete new design and application, tailored to meet the needs of REACH-affected stakeholders and built around a globally agreed data format, to enable IUCLID adopters not only to fulfil their REACH obligations, but also to re-use their data for other European and global programmes, leading to significant synergy effects and reduction of testing efforts.

IUCLID 5 is the tool stipulated by Article 111 of the REACH regulation according to which the chemicals industry is required to gather required properties and hazard data on their substances. IUCLID 5 must also be used to create REACH dossiers, to be submitted to the ECHA.

Without the timely availability of this central IT tool to more than 6000 REACH stakeholders, REACH could not have entered into force in June 2007.

The IUCLID 5 data model also features Biocides/Pesticides elements and data collected under REACH can thus be re-used, once complemented with data on biocidal or pesticidal properties, for data reporting obligations under the biocides legislation. Similarly, IUCLID 5 can be re-used to prepare dossiers for the OECD HPV Chemicals Programme.

[14] http://ecb.jrc.ec.europa.eu/iuclid/

Classlab Database

The Classification and Labelling of Dangerous Substances has been supported by the Classlab database. The database and the related application software consist of two parts: an official database, with the information published in Annex I of the DSD, and a working database which contains similar information for substances which are being considered for inclusion in Annex I or for which updates of existing information are being discussed. The database and the software have been improved several times. The databases can be consulted via a public web interface on the ECB website[15].

REACH-IT

The REACH-IT system is at the heart of the ECHA's operations and will provide a paperless system which will provide the capability necessary for the agency to undertake its work. It will also provide the necessary links for industry to submit their data and for the MS authorities to execute their tasks.

The JRC has undertaken the role of technical manager of the analysis and design of this system, supported by DG Enterprise and DG Environment who also fund a number of external contracts to support the work. With the creation of the ECHA, the project management was handed over to the agency. REACH-IT will become operational by June 2008.

New Chemicals Database

In 1994, the New Chemicals Database was installed at the premises of the ECB to support the notification of new substances scheme (see above, section on New Substances). From April 1995, the data collection for New Chemicals has been managed by the ECB. In the same way as HEDSET was used to input data to IUCLID, the DES program was used for New Chemicals. In parallel with the development of IUCLID 4.0, the NCD software was later rewritten in a client-server architecture similar to the architecture of IUCLID. As notified substances are regarded as registered under REACH the datasets of the NCD (ca. 8000) are being migrated into IUCLID 5, using a purpose-built migration tool.

EDEXIM

Also in 1994, the ECB started developing EDEXIM to support information exchange on the import and export of restricted chemicals (see below, section on Import/Export).

ECB website

To ensure that data on chemicals are also available to the public, the ECB website was created in 1997. Since 2002 it has become one of the world's most visited sites on chemical information, with more than 5400 unique visitors per day during 2007[16], and a peak of 7182 visitors on the date of entry into force of the REACH regulation (1 June 2007). In addition to overviews of the various ECB activities, the website provides access to ESIS, which is the online reference system for information on EU chemicals, EU risk assessment reports, the European Database Export Import of Dangerous Chemicals (EDEXIM), freely downloadable software tools (e.g. for computational toxicology, see below), and a large number (around 22 000) of documents.

OECD Global Portal

The OECD eChemPortal project was started in 2004 with the aim to establish a web portal that would provide uniform and homogenous access to data on the properties of chemical substances, stored in different participating national databases.The ECB is a member of the Steering Group of the eChemPortal project.

The project has already delivered a first version[17], which provides search functionality of substance names across eight databases, including ESIS from the ECB and databases from the USA, Japan, OECD and United Nations (UN). The web portal will be enhanced to provide search functionality not only for substance names, but also substance properties. This will provide the user with a more flexible searching capacity

The JRC will continue to collaborate closely in the future design and build of eChemPortal. This will include a project in which elements of the IUCLID 5 application can be re-used in the eChemPortal project: this will deliver the "IUCLID eChemPortal Provider Agent", the "IUCLID Web Interface" and related data formats necessary to exchange data across participant borders. There is also a synergy with the IUCLID Query Tool project being managed by the European Commission (DG Enterprise, DG Environment and JRC) and the ECHA with funding from DG Enterprise.

[15] http://ecb.jrc.ec.europa.eu/classification-labelling/search-classlab/

[16] A unique visitor is a host making at least 1 hit on 1 page of the website. If the host makes several visits, it is counted only once.

[17] http://webnet3.oecd.org/echemportal/

Tools for computational modelling

The ECB provides a range of freely downloadable (or accessible) software tools for modelling the effects and fate of chemicals by computational methods. In addition to EUSES (see above), these tools include: the hazard estimation software, Toxtree; the ranking software, DART; and the chemical similarity assessment tool, Toxmatch. In addition, information on the estimated properties of chemicals is available via the Danish QSAR Database, for which an internet-accessible version has been made available[18].

Future activities

As the REACH and the GHS Regulation repeals the 'old' chemicals legislation, the ECB will hand over three major databases to ECHA. All data regarding existing substances is being handed over to ECHA as a confidential IUCLID 4 version. All information concerning new notified substances is being handed over as NCD in IUCLID 5 format. Furthermore, the Classlab Database will be transferred to the ECHA.

Following 1 June 2008, as part of its scientific support to the chemicals legislation and as a service to the scientific community, the JRC will build on the success of ESIS to develop a web-based chemical information system associated with a range of modelling tools. In addition, the JRC will continue to support the Commission's contribution to the OECD Global Portal project.

TRAINING ACTIVITIES

Throughout its 15-year history, the ECB has played a significant role in the organisation, hosting and provision of training to facilitate the risk assessment of chemicals. In addition to contributing to training courses organised by third parties, the ECB has held a number of its own training courses covering the principles and methods of risk assessment, IUCLID, EUSES, EDEXIM and computational toxicology.

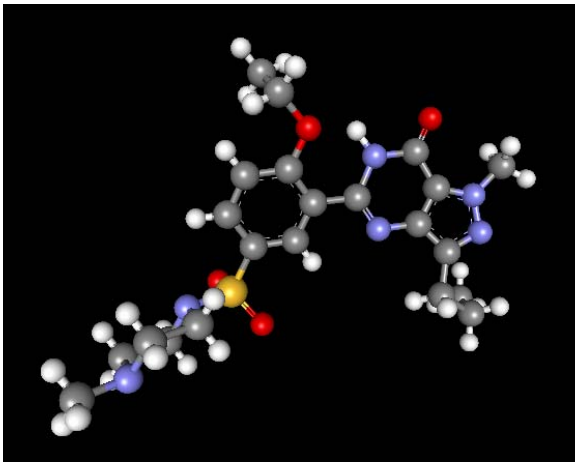
There has been a wide international participation in ECB training courses which have been attended by participants from MS authorities, industry (including Small and Medium Enterprises), Acceding and Candidate Countries, USA, Canada, and Japan, among others.

In addition to general courses, dedicated courses have been provided to encourage knowledge transfer. For example, between 2004 and 2007, knowledge transfer courses were held in Cyprus, the Czech Republic, Spain, Slovakia, Turkey, the Former Republic of Yugoslavia and Poland in collaboration with the corresponding Ministries of Health and Environment and in collaboration with the Dutch Institute of Risk Assessment Sciences (IRAS) and the National Institute for Public Health and Environment (RIVM).

Since 2000, courses on IUCLID 4 have provided training on how to complete and validate datasets for regulatory endpoints. For the new version, IUCLID 5, which was rolled out in 2007, a series of training courses were provided to highlight its new features, functionalities and potentialities. Courses on EUSES have focussed on emission estimation, environmental distribution, exposure and effect assessment, and on the characterisation of the risks posed to human heath and the environment by chemical substances. Several training courses have also been organised on EDEXIM.

Between 2005 and 2007, three courses on computational toxicology have aimed at promoting the acceptance and implementation of QSARs and related estimation methods. The ECB is also supporting the OECD in the development of training materials for the OECD QSAR Toolbox.

The JRC will continue to organise and contribute to training courses on the methods and tools needed for risk assessment, including training on Integrated Testing Strategies.



ECB ACTIVITIES TO BE CONTINUED WITHIN THE JRC

Biocides

Biocides are chemicals often referred to as non-agricultural pesticides or antimicrobials which are

[18] http://ecb.jrc.ec.europa.eu/qsar/qsar-tools/.

widely used in our society. Examples are disinfectants used in hospitals, wood preservatives, antifouling products used on ship hulls, rodenticides used in waste disposals and preservatives. The biocides industry involves a highly varied assortment of mainly small and medium-sized enterprises. Many active substances are used both in plant protection and biocidal products or have an industrial as well as biocidal use.

The European Union adopted separate legislation on biocides in 1998: *Directive 98/8/EC*, also known as the Biocidal Products Directive (BPD) [5]. The BPD defines biocidal products and sets out a frame for their evaluation in a two-step procedure where the first step is the entry of the active substances onto Annex I in a centralised process, and the second step is the authorisation of the products in which the active substances are used by Member States. Active substances are divided into new active substances, which cannot be placed on the market for biocidal purposes unless they are included in Annex I, and existing active substances, which go through the Review Programme. The Commission together with the Member States took two main initiatives to set up the framework for entering the active substances onto Annex I of the BPD. The first initiative was to ensure that guidance is available for industry and the authorities to fulfil the requirements of the BPD. The second initiative was to obtain an overview of substances to be assessed under the Review Program.

The ECB[19] has been involved in the technical implementation of the BPD from the start. The development of the above-mentioned guidance was coordinated by the ECB leading to seven different guidance documents published on the ECB website. In addition, the ECB has a coordinating role in the development of so-called Emission Scenario Documents for many product types assessed in the Review Program. The ECB also played an essential role in the identification and notification process leading to the list of active substances which are now being evaluated by the Member States, based on a dossier submitted by industry, in the Review Program. Finally, the ECB is responsible for the technical evaluation process by coordinating and chairing the Technical Meetings. To date, 25 meetings have taken place since the first one in 1999. About 50 dossiers for mainly wood preservatives and rodenticides have been finalised in the Technical Meetings.

Scientific and technical support to the biocides activity will be continued and further increased within the JRC.

Treatment of wood with a wood preservative

Export/Import of Dangerous Chemicals

The Rotterdam Convention on Prior Informed Consent (PIC) aims at reducing the risk connected with chemicals when they are internationally traded. The Convention sets up an internationally recognised scheme requiring importing countries to give PIC before certain hazardous substances and pesticides can be exported to them. The Convention, which was adopted on 10 September 1998 and entered into force on 24 February 2004, is implemented in the EU by *Regulation (EC) 304/2003* [6]. The Convention creates legally binding obligations for the implementation of the PIC procedure. It is based on the original and voluntary PIC procedure, which was jointly implemented by the United Nations (UN) Environment Programme (UNEP) and its Food and Agriculture Organisation (FAO) from 1989 and which ceased on 24 February 2006. The main difference between the Rotterdam Convention and the original PIC procedure is that the international procedure is now legally binding. Before the adoption of the Rotterdam Convention by the UN, *Regulation (EEC) 2455/92* was in force to implement the PIC procedure in EU legislation.

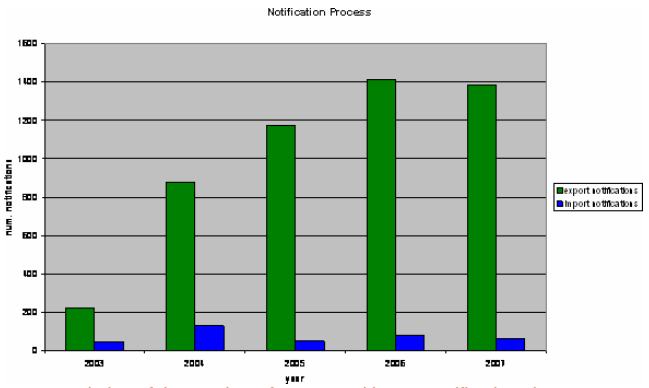
Since 1994, the ECB[20] has managed, on behalf of DG Environment, the information exchange on international trade of certain dangerous chemicals. The ECB created EDEXIM (European Database Export Import) with a public version in English, French and Spanish, and the Designated National Authority (DNA) version for export notification management and DNA information exchange.

The JRC continues its contribution to the DNA meetings at the EU level and to the meetings of the Conference of Parties and the Chemical Review Committee at the international level. The ECB has updated EDEXIM in accordance with the new Convention. Now EDEXIM is available also in German, Italian and Polish and is capable of

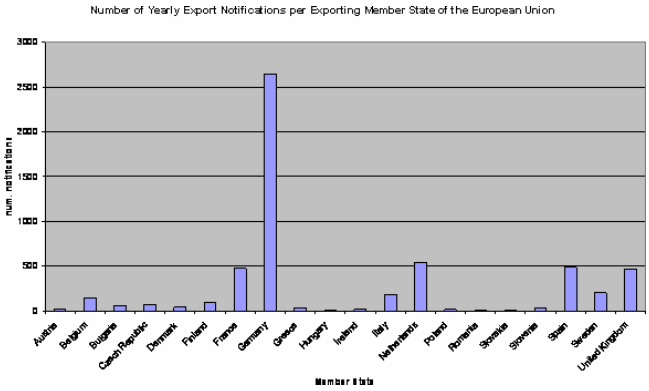
[19] http://ecb.jrc.ec.europa.eu/biocides/

[20] http://ecb.jrc.ec.europa.eu/import-export

managing a significantly increased number of chemicals as well as a further increase in the number of export notifications. To increase the efficiency of the overall process the interchange of information was opened to EU enterprises to allow exporters to enter export notifications directly into EDEXIM. In 2008, EDEXIM is being further adapted to the new EU legislation on Import and Export, in order to facilitate the monitoring and control of PIC chemicals.



Evolution of the number of export and import notifications by year



Distribution of export and import notifications by Member State

Testing Methods

EU harmonised and standardised testing methods constitute the basis for the evaluation of the hazardous properties of potentially dangerous chemical substances, both for C&L and risk assessment. Data generated using these methods are the starting point to assess chemicals regarding their possible effects both on human health and the environment. These methods play a central role in chemicals control in the EU and they are referred to in more than 20 pieces of EU legislation, e.g. legislation regulating dangerous substances and preparations, pesticides, biocides and cosmetics. These regulations constitute the core of EU policy to attain a high degree of protection for human health and the environment in the EU.

The harmonised testing methods are also important for ensuring proper functioning of the Single Market in the EU and allowing the free movement of goods between Member States by providing standardised datasets that are accepted by all Member States. In addition if these methods are accepted at a wider international level, they also contribute to the free movement of goods at a global level. For this reason, their development is closely linked and coordinated, in particular, with the parallel OECD Test Guidelines Programme.

Until the entry into force of REACH, in the EU, the legally recognised standardised Testing Methods to determine the hazardous properties of chemical substances are contained in Annex V of the DSD. Once included in Annex V, the results obtained with these methods are recognised by the regulators beyond doubt and with no need for further demonstration. In the future, a similar role is foreseen to be played by the Testing Methods Regulation (TMR), currently undergoing the process of approval.

Since 1995, the ECB[21] has coordinated the technical and scientific work needed for the development and introduction of EU harmonised standardised methods into Annex V of the DSD (and prepared all the methods to be included in the TMR, which is complementary to REACH). It is expected that the JRC will continue playing a similar role for REACH.

All this technical/scientific work has been (and will continue to be) carried out and coordinated by the ECB (JRC) in consultation and with the priceless help of the Group of the EU National Coordinators for Testing Methods, who are experts from the Member States supported by a further network of experts in their respective countries. The National Coordinators representing the MS CAs have advised the ECB on any issues related to Testing Methods, including the proposed testing protocol(s), work plan, priorities and preferred acceptance approach. In addition, the ECB benefited from the advice of other experts both inside and outside the Commission. Particularly worth mentioning is the close collaboration with the JRC's European Centre for Validation of Alternative Methods (ECVAM), which has resulted in a number of alternative methods included, or in the process of being included, in EU legislation as well as in the OECD Test Guidelines collection.

Regarding the collaboration with the OECD, the ECB has acted, by delegation from the Chemicals Unit of DG Environment, as the central coordinating point regarding the input of Commission in the Test Guideline Programme. The ECB has thus represented the Commission in these OECD

[21] http://ecb.jrc.ec.europa.eu/testing-methods

activities, and has supported the participation of DG Environment in other higher policy levels of OECD (e.g. the Joint Meeting). In addition, the ECB has chaired the meetings of the EU national Coordinators for Testing Methods, a forum that allows the coordination of the activities of the Member States related to Testing Methods, but which also acts as a focal point for coordinating the EU input into the OECD Test Guidelines Programme while respecting national independence. The EU National Coordinators Meeting (NCM) has ensured consistency and coordination of the opinions expressed by the Commission and the MS authorities with regard to the needs and priorities at EU level while, at the same time, providing an enhanced impact of the EU positions. A coordinated EU position has an extra weight in the OECD Working Group of National Coordinators of the Test Guidelines Programme (WNT), whose decisions are taken by consensus.

As a result of these tasks more than 52 new or updated methods have been introduced into EU legislation while several more are already in the pipeline, including four *in vitro* methods (skin corrosion, absorption, phototoxicity in 2000 and revised in 2007) and several reduction/refinement alternatives (acute toxicity in the 1990's and revised in 2004, skin sensitisation in 2004) and some more on the way. The pioneering deletion in 2001 of the classical LD_{50} Acute Toxicity Test from the EU regulation was followed soon afterwards by the deletion in 2004 of the same test in the OECD.

Also worth mentioning is the crucial role that the ECB played in the development of Integrated Testing Strategies through coordination as well as active input roles in the REACH Implementation Project (RIP 3.3) which produced the "Guidance for Industry on fulfilling the data requirements for REACH"[22].

After the hand-over of many traditional ECB activities to the ECHA, the JRC will continue to support REACH and the ECHA, in addition to providing support to other pieces of EU legislation on chemicals regarding standardisation and harmonisation of Testing Methods for Chemicals, in particular through the Testing Methods Regulation and a revamped National Coordinators Group. Continued collaboration with other groups in developing Integrated Testing Strategies and alternative (non-animal) approaches to chemical assessment, as well as tackling the new challenges posed by emerging new materials and technologies bear the promise of a challenging future.

Computational Toxicology, including Quantitative Structure Activity Relationships (QSARs)

With the increasing demand for reliable data on the properties,hazards and fate of chemicals, the application of valid *in silico* approaches has acquired a new significance. Such approaches can be used to prioritise chemical assessments and, in certain cases, they can be used directly to fill data gaps in hazard and risk assessments.

The overall aim of the Computational Toxicology activity within the ECB[23] is to promote the development, assessment, acceptance and implementation of computer-based methods suitable for the regulatory assessment of chemicals. This includes methods for predicting the effects of chemicals on human health and the environment, as well as their distribution and fate within the environment and biological organisms. Among the wide range of *in silico* approaches, particular emphasis has been placed on Quantitative Structure-Activity Relationships (QSARs), chemical grouping, chemometric ranking and molecular modelling.

Early JRC activities on QSARs started in the Environment Institute [24, 25] before the creation of the ECB and were continued within the ECB under the leadership of Dr Walter Karcher, the first Head of ECB. Notable achievements in these early years were: a) the organisation and hosting of the 6th *International Workshop on QSAR in Environmental Sciences* (Belgirate, 1994); b) the provision of QSAR estimates of the aquatic toxicity and degradation for each chemical listed on the EU List of Dangerous Substances; and c) an international collaboration with the USA and Japan to evaluate the US Government's QSAR models by using data on chemicals notified in the EU [26].[24]

The QSAR activity gained a new momentum in 2003, when the primary focus was to support the needs of REACH. Since then, the JRC has become a key player in the QSAR field [27, 28]. In collaboration with ECVAM [29], the ECB played a leading role in the establishment of internationally accepted principles and guidance for the validation of QSARs. Subsequently, the ECB developed guidance on the use of QSARs and chemical categories under REACH. In order to increase the EU capacity on QSARs, the ECB has organised training courses, and has developed a range of software tools which are freely available from the ECB website. The EU QSAR Working Group, comprising nominated experts from the MS authorities, Industry and other organisations,

[22] http://ecb.jrc.ec.europa.eu/reach/rip/

[23] http://ecb.jrc.ec.europa.eu/qsar/

[24] Further information on the US/EC Joint Project on Evaluation of (Q)SARs is given at: http://ecb.jrc.ec.europa.eu/qsar/background/

has played an important advisory and consensus building role in these activities. In addition, the ECB has made significant contributions to the scientific QSAR community. For example, during 2007 the Computational Toxicology Group wrote a series of reviews on the current status of computational methods for the assessment of chemicals, which has been published as a special issue in a peer-review scientific journal [30-37]. Another recent and significant achievement has been to generate chemical structures for approximately 69,000 of the EINECS chemicals[25], which will support both further research as well as the Registration process under REACH.

Following the hand-over of many traditional ECB activities to the ECHA, the Computational Toxicology Group will continue within the JRC to support REACH as well other pieces of EU legislation on chemicals. In addition to these policy-support activities, the group will pursue a vibrant research programme contributing to key challenges in computational toxicology and chemoinformatics, as well contributing to the development of alternative (non-animal) approaches to chemical assessment based on Integrated Testing Strategies.

The Relevance of ECB Work over 15 years

Policy Support	
Legislation in which ECB contribution is mentioned	ca 40
New Chemicals Notifications processed/updated per year	400 + 500
Biocides Notifications	1000
Import & Export notifications	>400 & >5500
Number of datasets in the New Chemicals Database	8000
Number of datasets in IUCLID	40050
Meetings organised	> 350
Meetings/Working Groups attended by ECB Staff	> 600
Coordination and input to Technical Guidance Documents for REACH	> 20
Scientific Output	
Risk Assessment Reports	85
Monographs and Guidance Documents	ca 40
Peer reviewed scientific papers	150
Book chapters	10
Training and Communication	
Training for staff to be recruited by ECHA	> 20
Training courses given/organised	ca 50
Invited presentations	ca 250
ECB newsletters	ca 30
Visits to ECB Web page (per day in 2007)	5 400
Number of enquiries	ca 5000

CONCLUSIONS

The JRC management and the ECB staff members are proud of the achievements obtained by the ECB during the last 15 years. We look forward to developing further scientific activities and collaborative networks in support of the chemicals legislation. We are confident that ECHA will be a great success as well!

Acknowledgements

The contributions to ECB activities of all current and former members of the ECB staff, too numerous to mention here, are gratefully acknowledged.

ECB staff in 2007

[25] http://ecb.jrc.ec.europa.eu/qsar/information-sources/

REFERENCES

1) European Commission (1993). Commission Communication to the Council and the European Parliament establishing the European Chemicals Bureau. Notice no. 93/C1/02. *Official Journal of the European Communities* C001. 5.01.93. p.3.

2) European Commission (2006). Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC. *Official Journal of the European Union*, L 396/1 of 30.12.2006.

3) European Commission (1967). Council Directive 67/548/EEC on the approximation of the laws, regulations and administrative provisions relating to the classification, packing and labelling of dangerous substances. *Official Journal of the European Communities* 196, 16.8.1967, p.1.

4) European Commission (1993). Council Regulation (EEC) No 793/93 on the evaluation and control of the risks of existing substances. *Official Journal of the European Communities* L 84, 5.4.1993, p.1.

5) European Commission (1998). Directive 98/8/EC of the European Parliament and of the Council of 16 February 1998 concerning the placing of biocidal products on the market. *Official Journal of the European Union*, L 132/1 of 24.04.1998.

6) European Commission (2003). Regulation of the European Parliament and of the Council of 28 January 2003 concerning the export and import of dangerous chemicals (EC) 304/2003. *Official Journal of the European Union*, L 63 of 6.3.2003, p.1.

7) European Commission (1979). Council Directive 79/831/EEC amending for the sixth time Directive 67/548/EEC on the approximation of the laws, regulations and administrative provisions relating to the classification, packing and labelling of dangerous substances. *Official Journal of the European Communities* L259, 15.10.79, p.10.

8) European Commission (1990). Commission communication pursuant to Article 13 of Council Directive Directive 67/548/EEC of 27 June 1967 on the approximation of the laws, regulations and administrative provisions relating to the classification, packing and labelling of dangerous substances, as amended by Directive 79/831/EEC – EINECS (European inventory of existing commercial substances). *Official Journal of the European Communities* C 146 A, 15.6.1990.

9) Allanou R, Hansen BG & van der Bilt Y (1999). Public Availability of Data on EU High Production Volume Chemicals. EC report no. EUR 18996 EN. European Commission-Joint Research Centre, Ispra, Italy.

10) Allanou R, Hansen BG & van der Bilt Y (2003). Public Availability of Data on EU High Production Volume Chemicals – Part 2. *Chimica Oggi* **59**, 91-95.

11) European Commission (2001). White paper on a Strategy for a future Chemicals Policy (COM (2001) 88 final).

12) European Commission (2003). Proposal for a Regulation of the European Parliament and of the council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency and amending Directive 199/45/EC and Regulation (EC) {on Persistent Organic Pollutants} (COM/2003/644 final).

13) European Commission (1992). Council Directive 92/32/EEC of April 1992 amending for the seventh time Directive 67/548/EEC on the approximation of the laws, regulations and administrative provisions relating to the classification, packing and labelling of dangerous substances. *Official Journal of the European Communities* L 154, 5.6.1992, p.1.

14) European Commission (1993). Commission Directive 93/67/EEC of 20 July 1993 laying down the principles for assessment of risks to man and the environment of substances notified in accordance with Council Directive 67/548/EEC. *Official Journal of the European Communities* L 227, 8.9.1993, p.9.

15) European Commission (1994). Commission Regulation 1488/94 (EC) of 28 June 1994 laying down the principals for the assessment of risks to man and the environment of existing substances in accordance with Council Regulation 793/93 (EC). *Official Journal of the European Communities* L 161, 29.6.1994, p.3.

16) Hansen BG, van Haelst AG, van Leeuwen K & van der Zandt P (1999). Priority setting for existing chemicals: European Union risk ranking method. *Environmental Toxicology & Chemistry* **18**, 772-779.

17) van Haelst AG & Hansen BG (2000). Priority setting for existing chemicals: automated data selection routine. *Environmental Toxicology & Chemistry* **19**, 2372-2377.

18) EC (1996). Technical Guidance Document in support of the Commission Directive 93/67/EEC on risk assessment for new notified substances and the Commission Regulation (EC) 1488/94 on risk assessment for existing substances. European Commission-Joint Research Centre, Ispra, Italy. Accessible from ECB website: http://ecb.jrc.it/tgd/

19) EC (2003). Technical Guidance Document on risk assessment in support of Commission Directive 93/67/EEC on risk assessment for new notified substances, Commission Regulation (EC) No. 27 1488/94 on risk assessment for existing substances, and Directive 98/8/EC of the European 28 Parliament and of the Council concerning the placing of biocidal products on the market. EC report no. EUR 20418 EN. European Commission-Joint Research Centre, Ispra, Italy. Accessible from ECB website: http://ecb.jrc.it/tgd/

20) Pedersen F, de Bruijn J, Munn SJ, Van Leeuwen K (2003). Assessment of additional testing needs under REACH. Effects of (Q)SARs, risk based testing and voluntary industry initiatives. EC report no EUR 20863 EN. European Commission-Joint Research Centre, Ispra, Italy.

21) van der Jagt K, Munn S, Tørsløv J & de Bruijn J (2004). Alternative approaches can reduce the use of test animals under REACH. EC report no EUR 21405 EN. European Commission-Joint Research Centre, Ispra, Italy.

22) Heidorn CJA, Hansen BG & Nørager O (1996). IUCLID: A Database on Chemical Substances Information as a Tool for the EU-Risk-Assessment Program. *Journal of Chemical Information and Computer Sciences* **36**, 949-954.

23) Heidorn CJA, Rasmussen K, Hansen BG, Nørager O, Allanou R, Seynaeve R, Scheer S, Kappes D & Bernasconi R (2003). IUCLID: An Information Management Tool for Existing Chemicals and Biocides. *Journal of Chemical Information and Computer Sciences* **43**, 779-786.

24) Karcher W & Devillers J (eds) (1990). *Practical Applications of Quantitative Structure-Activity Relationships (QSAR) in Environmental Chemistry and Toxicology*. Kluwer, Dordrecht.

25) Coccini T, Giannoni L, Karcher W, Manzo L & Roi R (1992). Quantitative Structure-Activity Relationships (QSAR) in

Environmental Chemistry and Toxicology. EC report no. EUR 14308 EN. European Commission-Joint Research Centre, Ispra, Italy.

26) Karcher W, Hansen BG, Van Leeuwen C, Wagner P & Auer C (1995). Predictions for Existing Chemicals-A Multilateral QSAR Project. *SAR and QSAR in Environmental Research* **3**, 217 – 221.

27) Worth AP, Bassan A, de Bruijn J, Gallegos Saliner A, Netzeva T, Patlewicz G, Pavan M, Tsakovska I & Eisenreich S (2007). The role of the European Chemicals Bureau in promoting the regulatory use of (Q)SAR methods. *SAR and QSAR in Environmental Research* **18**, 111-125.

28) Worth AP, van Leeuwen CJ & Hartung T (2004). The prospects for using (Q)SARs in a changing political environment - high expectations and a key role for the Commission's Joint Research Centre. *SAR and QSAR in Environmental Research* 15, 331-343.

29) Worth AP, Hartung T & van Leeuwen CJ (2004). The role of the European Centre for the Validation of Alternative Methods (ECVAM) in the validation of (Q)SARs. *SAR and QSAR in Environmental Research* 15, 345-358.

30) Bassan A & Worth AP (2008). The Integrated Use of Models for the Properties and Effects of Chemicals by means of a Structured Workflow. *QSAR & Combinatorial Science* **27**, 6-20.

31) Cronin MTD & Worth AP (2008). (Q)SARs for Predicting Effects Relating to Reproductive Toxicity. *QSAR & Combinatorial Science* **27**, 91-100.

32) Gallegos Saliner A, Patlewicz G & Worth AP (2008). A Review of (Q)SAR Models for Skin and Eye Irritation and Corrosion. *QSAR & Combinatorial Science* **27**, 49-59.

33) Netzeva TI, Pavan M & Worth AP (2008). Review of (Quantitative) Structure-Activity Relationships for Acute Aquatic Toxicity. *QSAR & Combinatorial Science* **27**, 77-90.

34) Patlewicz G, Aptula AO, Roberts DW & Uriarte E (2008). A Minireview of Available Skin Sensitization (Q)SARs/Expert Systems. *QSAR & Combinatorial Science* **27**, 60-76.

35) Pavan M, Netzeva TI & Worth AP (2008). Review of Literature-Based Quantitative Structure-Activity Relationship Models for Bioconcentration. *QSAR & Combinatorial Science* **27**, 21-31.

36) Pavan & Worth AP (2008). Review of Estimation Models for Biodegradation. *QSAR & Combinatorial Science* **27**, 32-40.

37) Tsakovska I, Lessigiarska I, Netzeva T & Worth AP (2008). A Mini Review of Mammalian Toxicity (Q)SAR Models. *QSAR & Combinatorial Science* **27**, 41-48.

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Abstract
From its creation in 1993, the European Chemicals Bureau (ECB) has played a vital role in the development, implementation and monitoring of European Union legislation on chemicals and contributing to the Commission's international participation in chemicals programmes.

The ECB has housed much of the European Commission's experience, capacity and historical memory in chemical risk assessment and safe chemical management. The contribution of ECB to the drafting, development and implementation of the REACH regulation has been an important one. The provision of scientific/technical expertise to the start-up phase of the newly born European Chemicals Agency has been essential for a swift and effective implementation of REACH. The ECB has contributed to that effort not only by selecting, recruiting and training ECHA staff but also by seconding part of its own key staff to the agency. And finally, during 2008 the ECB is completing the hand-over files and transmitting them to the ECHA, which is taking over responsibility for the operational implementation of EU legislation on chemicals.

This report, which is produced on the 15th anniversary of the ECB, provides a historical overview of ECB's scientific and policy support activities since its establishment in 1993 as part of the European Commissions' Joint Research Centre (JRC).

The mission of the JRC is to provide customer-driven scientific and technical support for the conception, development, implementation and monitoring of EU policies. As a service of the European Commission, the JRC functions as a reference centre of science and technology for the Union. Close to the policy-making process, it serves the common interest of the Member States, while being independent of special interests, whether private or national.